

Full Text AR-94-002

OSTEOPOROSIS/RELATED BONE DISEASES INFORMATION RESOURCE CENTER

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Health and Safety Education

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Letter of Intent Receipt Date: November 1, 1993

Application Receipt Date: December 21, 1993

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for the purpose of establishing a resource center for osteoporosis, Paget's disease, and related bone disorders to facilitate and enhance knowledge and understanding on the part of health professionals, patients, and the public through effective dissemination of information.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Osteoporosis/Related Bone Diseases Resource Center, is related to the priority area of educational and community-based programs. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-

0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by individuals representing domestic or foreign non-profit entities involved in activities regarding the prevention and control of osteoporosis and related bone disorders. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) Education Project Grant (R25). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA may not exceed four years. The anticipated award date is June 30, 1994.

FUNDS AVAILABLE

The estimated funds (total costs) available for the first year of support are \$500,000 total cost. The NIAMS expects to make one award.

RESEARCH OBJECTIVES

Background

Osteoporosis is an important public health problem in which weakened bones are easily fractured. More than 1.3 million fractures each year are attributable to osteoporosis. Death is a frequent occurrence in the months immediately following hip fracture. Fifty percent of surviving individuals will need help with daily living activities, and 15 to 25 percent will need to enter a long-term care institution shortly after the fracture. In 1986 the annual national cost of osteoporosis-related fractures was 7 to 10 billion dollars. Although accurate national cost and personal impact data are less available for drug-induced osteoporosis, other secondary types of osteoporosis, Paget's disease, osteogenesis imperfecta, and other bone diseases these diseases are also important problems.

In the past decade there have been extraordinary advances in the understanding of basic bone biology leading to very targeted approaches both in the prevention and effective treatment of

several types of osteoporosis and related bone diseases, but wide application to clinical care has lagged behind. Further education of health care professionals, patients, and the public at large is needed. In particular, the teaching of osteoporosis prevention to children and adolescents and the need to reach all segments of an ethnically, economically, and geographically diverse American population have been identified as priorities.

The National Institutes of Health Revitalization Act of 1993 [P.L. 103-43] provided for "the establishment of an information clearinghouse on osteoporosis and related bone disorders to facilitate and enhance knowledge and understanding on the part of health professionals, patients, and the public through the effective dissemination of information." The law further requires that such a clearinghouse be established through "a grant, cooperative agreement, or contract with a non-profit private entity involved in activities regarding the prevention and control of osteoporosis and related bone disorders."

Objective

The objective of this RFA is to establish an information resource center to reach health professionals, patients and the public with state-of-the-art information on the prevention and treatment of osteoporosis and related bone diseases. This will include evaluation of the Center's ability to effect beneficial changes in one or more of the target groups who receive the information.

Bone disease topics addressed by the Center might include, but are not limited to: post-menopausal osteoporosis; osteoporosis in men; osteoporosis in high-risk populations; osteoporosis in hard to reach populations, including minority, low income, rural, or non-English speaking populations; corticosteroid-induced osteoporosis; and similar projects for Paget's disease, osteogenesis imperfecta, and other bone diseases.

Populations targeted by the Center might be: health care professionals, including school nurses or biology teachers, state or local public health officials, nutrition professionals, physicians, pharmacists, or others; patient groups, either disease specific or general, such as retirement groups; the public at large, including age-specific populations, such as adolescents. Prevention awareness initiatives, including hip fracture prevention, are encouraged.

Applicants should describe the methodology by which they will evaluate the efficacy of their educational activities.

Specific questions that might be addressed include:

- o What are effective ways of making adolescent girls aware of healthy diets and habits for prevention of future osteoporosis?
- o Which health care providers are the most effective teachers regarding healthy bone?
- o What methods are effective for changing knowledge in a diverse population?

These are illustrative only, and are neither exclusive nor restrictive. The applicant may select any area(s) of interest that concerns the prevention, treatment, and dissemination of information about osteoporosis and/or related bone diseases.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues must be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 (rev. 9/91) in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations

(i.e., Native Americans [including American Indians or Alaskan Natives], Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including, but not limited to, clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

LETTER OF INTENT

Prospective applicants are asked to submit, by November 1, 1993, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NIAMS staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Dr. Tommy Broadwater
Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 404
Bethesda, MD 20892
Telephone: (301) 594-9957
FAX: (301) 594-9673

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Information, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/435-0714; and from the NIH program administrator named below.

The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2a of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to:

Dr. Tommy Broadwater
Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 403
Bethesda, MD 20892

Applications must be received by December 21, 1993. If an application is received after that date, it will be returned to the applicant without review. The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by DRG and responsiveness by the NIAMS. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, ICD staff will contact the applicant to determine whether to return the application.

Applications may be triaged by the NIAMS peer review group on the basis of relative competitiveness. The NIH will withdraw from further competition those applications judged to be non-competitive for award and notify the applicant Principal Investigator and institutional official. Those applications judged to be competitive will undergo further scientific merit review. Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the ICD. The second level of review will be provided by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Review criteria include:

- o merit and originality of proposed projects;
- o qualifications and experience of the Principal Investigator and staff;
- o availability of the resources necessary to perform the project;

- o appropriateness of the proposed budget and duration in relation to the proposed project;
- o ability to reach target populations;
- o ability to evaluate the efficacy of the projects.

AWARD CRITERIA

The anticipated date of award is June 30, 1994.

The award criteria are:

- o priority score
- o availability of funds
- o programmatic priorities

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged.

The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Joan McGowan
Bone Biology and Bone Diseases Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 403
Bethesda, MD 20892
Telephone: (301) 594-9957
FAX: (301) 594-9673

Direct inquiries regarding fiscal matters to:

Ms. Carol G. Clearfield
Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 725B
Bethesda, MD 20892
Telephone: (301) 594-9973

FAX: (301) 594-9950

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research. Awards will be made under authorization of the Public Health Service Act, Title III, Section 301 (Public Law 410, 78th Congress, as amended, 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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